



Course Specification of Biopharmaceutics

I. Course Identification and General Information:					
1	Course Title:	Biopharmaceutics			
2	Course Number & Code:	Ph2711			
3	Credit hours: 3 hrs	C.H			
		Theoretic al	Practic al	Train ing	Semin ar
		2	2		3
4	Study level/ semester at which this course is offered:	Fourth year/ First semester			
5	Pre –requisite (if any):	Pharmaceutics I-IV			
6	Co –requisite (if any):				
7	Program (s) in which the course is offered:	Bachelor of Pharmacy			
8	Language of teaching the course:	English			
9	The department in which the course is offered:	Pharmaceutics and Industrial Pharmacy			
10	Location of teaching the course:	Faculty of Pharmacy-Sana'a University			
11	Prepared by:	Prof Dr / Mahmoud Mahyooob Alburyhi			
12	Date of approval:				

II. Course description:

This course aims to provide students with a comprehensive theoretical foundation of biopharmaceutics in new drug design. It examines the interrelationship of the physical / chemical properties of the drug, the dosage form (drug product) in which the drug is given, and the route of administration on the rate and extent of systemic drug absorption. It is intended tenable students to develop and select the dosage form that will provide a consistent bioavailability at desirable rate especially for narrow therapeutic index drugs.



III. Intended Learning Outcomes (ILOs) of the Course:

At the end of this course, the students will be able to:

1. Describe the ADME and the mechanisms of gastrointestinal absorption of drugs.
2. Discuss the factors affecting gastrointestinal absorption of drugs.
3. Identify the role of dosage form on drug bioavailability.
4. Identify the factors affecting drug absorption, distribution and elimination.
5. Identify bioavailability and bioequivalence.
6. Utilization the effect of absorption, distribution, metabolism, and excretion (ADME) of drugs in the body for dosage optimization and evaluating drug dosage regimen.
7. Demonstrate the biopharmaceutical considerations in drug product design.
8. Recognize the relationship between product design and the drug absorption, distribution and elimination.
9. Predict the effect of excipients and food on drug absorption, distribution and elimination.
10. Analyze the results of the in-vitro and in-vivo studies.
11. Assess physicochemical characteristics of drug substances as a factor affecting drug absorption.
12. Analyze bioavailability and bioequivalence studies.
13. Examine the biopharmaceutical consideration in dosage form design.
14. Communicating the dosage adjustment with physicians, suggesting therapeutic monitoring plans for physicians and use different information sources to solve medication problems.
15. Retrieve information from a variety of sources, including libraries, databases and internet.
16. Work effectively in a team and demonstrate time management skills.

IV. Intended learning outcomes (ILOs) of the course:

(A) Knowledge and Understanding:

Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in:
Knowledge and Understanding.

**Program Intended Learning Outcomes
(Sub- PILOs) in:
Knowledge and Understanding**

**Course Intended Learning Outcomes (CILOs) in:
Knowledge and Understanding**



After completing this program, students will be able to:		After completing this course, students will be able to:	
A1-	Recognize the principles of physical, chemical, clinical, social, behavioral, health and pharmaceutical sciences.	a1-	Describe the ADME and the mechanisms of gastrointestinal absorption of drugs.
A3-	Describe the general cellular, biochemical and physiological aspects of human body and recognize the pharmacokinetics, pharmacodynamics, disease pathophysiology, and pharmacogenetic of therapeutic agents to provide pharmaceutical care and facilitate management of patient's medication, rationalize drug use and overall health needs.	a2-	Discuss the factors affecting gastrointestinal absorption of drugs.
A4	Recognize the pharmaceutical dosage form design and the quality control of pharmaceutical formulations according to GMP and pharmacopeial requirements to support the pharmaceutical industries and research	a3-	Identify the role of dosage form on drug bioavailability.
A5	Demonstrate the basic knowledge of pharmacoconomics, pharmacovigilance, policy, legislation, marketing, administration and distribution of pharmaceutical and cosmetic products as well as ethics of health care	a4-	Identify the factors affecting drug absorption, distribution and elimination.
		a5-	Identify bioavailability and bioequivalence.

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment of Learning Outcomes of Knowledge and Understanding to Teaching and Assessment Methods:

Course Intended Learning Outcomes (CILOs) in Knowledge and Understanding	Teaching strategies/methods to be used	Methods of assessment
completing this course, students will be able to:		



a1-	Describe the ADME and the mechanisms of gastrointestinal absorption of drugs.	Lectures, and group discussion	Attendance, Written, oral exams and small projects
a2-	Discuss the factors affecting gastrointestinal absorption of drugs.		
a3-	Identify the role of dosage form on drug bioavailability.		
a4-	Identify the factors affecting drug absorption, distribution and elimination.		
a5-	Identify bioavailability and bioequivalence.		

(B) Intellectual Skills:

Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: **Intellectual skills**

Program Intended Learning Outcomes (Sub-PILOs) in Intellectual skills		Course Intended Learning Outcomes (CILOs) of Intellectual Skills	
After completing this program, students will be able to:		After completing this course, students will be able to:	
B1	Consolidate the chemical, biochemical and physiological principles to construct the pharmacophores of the structure and their effect on the stability, pharmacokinetic and pharmacodynamic profiles of the drug.	b1-	Utilization the effect of absorption, distribution, Metabolism, and excretion (ADME) of drugs in the body for dosage optimization and evaluating drug dosage regimen.
B3	Design different types of safe and effective pharmaceutical dosage forms and develop novel methods of qualitative and quantitative analytical and biological analysis for pharmaceutical and biopharmaceutical products that support pharmaceutical research.	b2-	Demonstrate the biopharmaceutical considerations in drug product design.
B5	Interpret the prescriptions, patient and clinical data, Analysis all the encountered pharmaceutical problems and plan the strategies for their solution, to develop the health care.	b3-	Developing dosing regimens for the individualization of therapy for the patient.

Teaching And Assessment Methods For Achieving Learning Outcomes:



Alignment of Learning Outcomes of Intellectual Skills to Teaching Methods and Assessment Methods:		
Course Intended Learning Outcomes (CILOs) in Intellectual Skills.	Teaching strategies/methods to be used	Methods of assessment
After completing this course, students will be able to:		
b1- Utilization the effect of absorption, distribution, Metabolism, and excretion (ADME) of drugs in the body for dosage optimization and evaluating drug dosage regimen.	Lectures, solving problem brainstorming and group discussion	Project, homework, Written, oral exams and small projects
b2- Demonstrate the biopharmaceutical considerations in drug product design.		
b3- Recognize the relationship between product design and the drug absorption, distribution and elimination.		
b4- Predict the effect of excipients and food on drug absorption, distribution and elimination.		

(C) Professional and Practical Skills:			
Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: Professional and Practical Skills			
Program Intended Learning Outcomes (Sub-PILOs) in Professional and Practical Skills		Course Intended Learning Outcomes (CILOs) in Professional and Practical Skills	
After completing this program, students will be able to:		After completing this course, students will be able to:	
C1	Operate different pharmaceutical equipments and instruments and use emerging technologies in design, synthesis, pre-formulation, formulation, packaging, storage and analysis of pharmaceutical products according to GLP, GSP and cGMP guidelines.	c1-	Analyze the results of the in-vitro and in-vivo studies.
C3	Extract, isolate, purify, identify and formulate the natural products and assure their rational use.	c2-	Assess physicochemical characteristics of drug substances as a factor affecting drug absorption.
		c3-	Analyze bioavailability and bioequivalence studies.



C4	Provide patient-oriented pharmaceutical care by collaboration with other health care professionals to optimize therapeutic outcomes.	c4-	Examine the biopharmaceutical consideration in dosage form design.
C5	Conduct research studies and utilize the results in different pharmaceutical fields.		

Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment of Learning Outcomes of Professional and Practical Skills to Teaching and Assessment Methods:		
Course Intended Learning Outcomes (CILOs) in Professional and Practical Skills	Teaching strategies/methods to be used	Methods of assessment
After completing this course, students will be able to:		
c1-	Lectures , practical, discussion and brain storm	Written, practical, oral exams, report, project and observation.
c2-		
c3-		
c4-		
	Examine the biopharmaceutical consideration in dosage form design.	

(D) General / Transferable Skills:

Alignment of Course Intended Learning Outcomes (CILOs) to Program Intended Learning Outcomes (PILOs) in: General and Transferable skills	
Program Intended Learning Outcomes (PILOs) in General / Transferable skills	Course Intended Learning Outcomes (CILOs) in General / Transferable skills
After completing this program, students will be able to:	
D2	d1-
D3	d2
D4	d3



Teaching And Assessment Methods For Achieving Learning Outcomes:

Alignment of Learning Outcomes of General and Transferable skills to Teaching and Assessment Methods:

Course Intended Learning Outcomes (CILOs) in General and Transferable Skills		Teaching strategies/methods to be used	Methods of assessment
After completing this course, students will be able to:		Lectures , practical, discussion and brain storm	Written, practical, oral exams, report, project and observation.
d1-	Communicate the dosage adjustment with physicians, suggesting therapeutic monitoring plans for physicians and use different information sources to solve medication problems.		
d2-	Retrieve information from a variety of sources, including libraries, databases and internet.		
d3	Work effectively in a team and demonstrate time management skills.		

V. Course Content:

1 – Course Topics/Items:

a – Theoretical Aspect

Order	Topic List / Units	CILOs (symbols)	Sub-topic List	Number of weeks	Contact hours
1	Introduction to Biopharmaceutics , Pharmacokinetic, Pharmacodynamic And Clinical Pharmacokinetics	a1,a2,a3, b1,b2,b3,b4, d1	Definitions, Define pharmacokinetics and describe how pharmacokinetics is related to pharmacodynamics and drug toxicity, parameters and Mechanisms	1	2
2	Drug Absorption, Mechanisms of Drug Absorption	a1,a2, b1,b2,b3, b4,d1,d2,d3	Definition, Mechanisms of drug absorption	1	2



			process, factors affecting absorption		
3	Physiologic Factors Related to Drug Absorption	a3,a4, b2,b3,b4, d1,d2,d3	Types of factors pH, gastric and GIT factors	1	2
4	Physiochemical Factors Related to Drug Absorption	a4, b2,b3,b4, d1,d2,d3	Nature of drug, drug solubility, dissolution and drug stability	1	2
5	Biopharmaceutical Aspects of the Active Pharmaceutical Ingredient and Pharmaceutical Equivalence	a4, b2, d1,d2,d3	Formulation factors, method of manufacture, excipients, drug dosage and dosage regimen	1	2
6	Drug Distribution Physiologic Drug Distribution and Protein Binding	a4, b1,b2,b3,b4, d1,d2,d3	Definition, parameters, volume of distribution, Mechanisms , factors and Clinical Application	1	2
7	Mid-term Exam	a1-4, b1-4		1	2
8	Drug Metabolism	a3,a4,a5, b1,b2,b3,b4 d1,d2,d3	Definition and parameters,	1	2
9	Pharmacogenetics and Drug Metabolism	a5, b3,b4, d1,d2,d3	Mechanisms, classification and factors	1	2
10	Drug Excretion	a5, b1,b2,b3,b4, d1,d2,d3	Definition and parameters,	1	2
11	Drug Elimination, Clearance, and Renal Clearance	a4, b3,b4, d1,d2,d3	Mechanisms, classification and factors	1	2
12	Drug Elimination and Hepatic Clearance	a4, b3,b4, d1,d2,d3	Mechanisms, types and factors	1	2



13	Bioavailability	a2,a3,,a5, b1,b2,b3, b4,d1,d2,d3	Definition, classification, Relative bioavailability, Absolute bioavailability parameters and evaluations	1	2
14	Bioavailability and Bioequivalence	a2,a3, b1,b2,b3,b4, d1,d2,d3	Model parameters , drug absorption and bioavailability of dosage forms.	1	2
15	Biopharmaceutic Considerations In Drug Product Design And In Vitro Drug Product Performance	a3, b1,b2,b3, d1,d2,d3	Pharmaceutical alternative, Pharmaceutical equivalent	1	2
1.	final-term Exam	a1-5, b1-4		1	2
Number of Weeks /and Units Per Semester				16	32

b- Practical Aspect:				
Order	Practical Tasks	CILOs (symbols)	Number of weeks	Contact hours
1	Biopharmaceutic Considerations in Drug Product Design	c1, d1,d2,d3	1	2
2	Practice How Stomach Emptying, GI Residence Time, and Gastric Window Affect Drug Absorption	c1,c2,c3,c4, d1,d2,d3	1	2
3	Determine the Drugs for Which Gastric Ph Can Affect Bioavailability	c1,c2,c3, d1,d2,d3	1	2
4	Determine the Particle Size, Crystal Form, Solubility, Dissolution, and Ionization Affect in Vivo Dissolution and Absorption.	c1,c2,c3,c4, d1,d2,d3	1	2
5	Dissolution Test Methods And Relation to in Vivo Performance.	c1,c2,c3,c4, d1,d2,d3	1	2
6	Determine the Simulating Drug Distribution in the Body	c1,c2,c3,c4, d1,d2,d3	1	2



7	Mid-Term Exam	c1-4	1	2
8	Determine the Formulation Factors and Manufacturing Method Affecting PE And TE.	c2,c3,c4, d1,d2,d3	1	2
9	Practice Use Plasma Or Urine Data to Calculate Fraction of Drug Excreted and Metabolized.	c2,c3,c4, d1,d2,d3	1	2
10	Practice Use Plasma or Urine Data to Calculate Fraction Of Drug Excreted and Metabolized.	c2,c3,c4, d1,d2,d3	1	2
11	Practice Application of the Physiologically Factors Include Understanding the Effect Of Renal Impairment	c1,c2,c3,c4, d1,d2,d3	1	2
12	Practice Drug Elimination and Hepatic Clearance Application of the Physiologically Factors Include Understanding the Effect Of Hepatic Clearance	c4, d2 d1,d2,d3	1	2
13	Determine The Methods of Drug Excretion From the Body	c4, d1,d2,d3	1	2
14	Determine the Select API From Multiple Sources While Meeting PE (Pharmaceutical Equivalence) and TE (Therapeutic Equivalence) Requirement as Defined in CFR. How Pharmaceutical Equivalence Affects Therapeutic Equivalence and Pharmaceutical Alternatives.	c1-4, d1,d2,d3	1	2
15	Bioavailability and Bioequivalence Test Methods, and Analysis.	c2-4, d1,d2,d3	1	2
1.	Final-term Exam	c1-4	1	2
Number of Weeks /and Units Per Semester			16	32

VI- a-Teaching Strategies of the Course:



Lecture method, Group Discussion, Problem solving sessions, tutorials, brainstorming and Practical sessions.

b- Assessment Methods:

Oral Exam, Quizzes, Attendance, Participation, Short answers, reports, homework, Written exam, Practical works, practical exam and practical reports.

VII. Assignments:

No.	Assignments	Aligned CILOs (symbols)	Week Due	Mark
1	Homework Assignments	a1-5, b1-4, d1-3	Sporadic through the semester	10
2	Reports	c1-4, d1-3		

VIII- Schedule of Assessment Tasks for Students During the Semester:

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes (CILOs symbols)
1.	Attendance, Participation and quizzes	All Weeks	10	7%	a1-5,b1-4, d1-3
2.	Oral Tests and Homework-assignments	Sporadic through the semester	10	7%	a1-5, b1-4, d1-3
3.	Attendance, Practical Reports	All Weeks	15	10%	c1-4
4.	Practical mid-semester exam	7 th	15	10%	c1-4
5.	Theoretical mid-semester exam	7 th	30	20%	a1-4, b1-4
6.	Final Exam (theoretical)	16 th	50	33%	a1-5, b1-4



7.	Final Exam (practical)	16 th	20	13%	c1-4
Total			150	100%	

IX. Students' Support:

Office Hours/week	Other Procedures (if any)
2 hours per week	

X. Learning Resource (MLA style or APA style)S:

1- Required Textbook(s) (maximum two)

- 1- Notes on biopharmaceutics prepared by the department staff.
- 2-Shargel, L and Yu, ABC., 2016, *Applied Biopharmaceutics & pharmacokinetics*, 7th edition, McGraw-Hill Education, New York.
- 3-Bauer, LA, 2008, *Applied clinical pharmacokinetics*, 2nd edition, McGraw-Hill Companies, Inc, New York.

2- Recommended Readings and Reference Materials

- 1-Rowland M, Tozer T, 1995, *Clinical Pharmacokinetics—Concepts and Applications*, 3rd ed, Lea & Febiger, Philadelphia.
- 2-Levine RR, 1990, *Drug Actions and Reactions*, 4th ed., Little, Brown, Boston.
- 3- Gibaldi, M. (1991) *Biopharmaceutics and Clinical Pharmacokinetics*, 4th edn. Lea & Febiger, Philadelphia.

3- Electronic Materials and Web Sites etc.

www.pubmed.com
<http://www.sciencedirect.com/>

4- Other Learning Material:

J Pharmacokinet Biopharm
J Pharm Sci
Published articles related to the discussed topics



<p>United States Pharmacopeia and National Formulary (latest edition) United States Pharmacopoeial Convention Inc., Rockville, MD. British Pharmacopoeia (latest edition), HMSO. London. Martindale, W. (latest edition) The Extra Pharmacopoeia., Royal Pharmaceutical Society Great Britain, London.</p>
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XI. Facilities Required:

1 - Accommodation:	<ul style="list-style-type: none"> - Well-equipped lecture halls with data show facilities, whiteboards, etc. - Well-equipped laboratories with all required equipment and slide.
2 - Computing resources:	<ul style="list-style-type: none"> - Computer laboratory with internet facilities.

XII. Course Improvement Processes:

1- Strategies for obtaining student feedback on effectiveness of teaching	
	<ul style="list-style-type: none"> ▪ Student-based assessment of the effectiveness of teaching using a questionnaire designed by the Quality Assurance Unit at the end of the semester. ▪ Meeting with students and faculty (once per semester).
2- Other Strategies For Evaluation of Teaching by the Instructor or by the Department	
	<ul style="list-style-type: none"> ▪ Assessment of the course syllabus and contents by the teachers using a questionnaire designed by the Quality Assurance Unit of the university at the end of the semester. ▪ Regular meeting and discussion of the course content between the Head of Department and the teaching staff of the course (for theory and practice).
3- Processes for Improvement of Teaching.	
	<ul style="list-style-type: none"> ▪ Revision of the course specification and its teaching strategies every three academic years after consideration of all issues raised by the teachers and/or students during regular meetings and discussions. ▪ Exploring any possible defects in the course that might be encountered by the teaching staff and their mitigation in subsequent improved versions of course specification.
4- Processes for Verifying Standards of Students' Achievement	
	<ul style="list-style-type: none"> ▪ Checking of a sample of students' work by an independent faculty member. ▪ Periodic exchange and check marking of a sample of students' assignments with a faculty member from another institution. ▪ Adoption of scoring rubrics to assess the students' achievement (both for ongoing or summative assessments).



	<ul style="list-style-type: none"> Regular follow-up of laboratory logbooks to assess the practical achievement of students.
5- Procedures for Periodically Reviewing of Course Effectiveness and Planning for Improvement	
	<ul style="list-style-type: none"> Student rating and feedback Peer rating and feedback Regular meeting of the Curriculum Committee of the faculty.
6- Course Development Plans	
	<ul style="list-style-type: none"> Conducting regular workshops for the staff for improving their course specification skills. Regular revision of course specification and syllabus items.

6- Course Policies:	
1	Class Attendance: <ul style="list-style-type: none"> Attendance of all lectures and practical sessions is required. Unexcused absence exceeding 25% of the lectures or practical sessions will disqualify the student from entering the final exam.
2	Tardiness: <ul style="list-style-type: none"> Non-reasonable frequent tardiness will be allowed and is considered as absence from the lectures/
3	Exam Attendance/Punctuality: <ul style="list-style-type: none"> Exam attendance is obligatory unless being excused by the department and faculty. Absence from assignments or exams will be dealt with according to the general policy of the university.
4	Assignments & Projects: <ul style="list-style-type: none"> Assignments: Written and oral; Laboratory logbook signed by the responsible demonstrator. Projects: Not applicable.
5	Cheating: <ul style="list-style-type: none"> Punishment of cheating will be according to the general policy of the university in this respect.
6	Plagiarism: <ul style="list-style-type: none"> Plagiarism in written essays, reports, etc. is not accepted, and students who plagiarize the works of others will be punished according to the general policy of the university.
7	Other policies:



- General policies of the Students' Affairs of the University and the Quality Assurance Unit.



Course Plan of Biopharmaceutics

I. - Information about Faculty Member Responsible for the Course:							
Name of Faculty Member	Prof Dr/ Mahmoud Mahyoob Alburyhi	Office Hours					
Location & Telephone No.	777970600	SAT	SUN	MON	TUE	WED	THU
E-mail	buryhi@yahoo.com			2hrs	2hrs		

II. Course Identification and General Information:					
1-	Course Title:	Biopharmaceutics			
2-	Course Number & Code:	Ph2711			
3-	Credit hours: 3hrs	C.H			Total
		Th.	Seminar	Pr.	
		2	-	2	3
4-	Study level/year at which this course is offered:	Fourth year/First semester			
5-	Pre –requisite (if any):	Pharmaceutics I-IV			
6-	Co –requisite (if any):				
7-	Program (s) in which the course is offered	Bachelor of Pharmacy			
8-	Language of teaching the course:	English			
9-	System of Study:	Semesters			
10-	Mode of delivery:	Regular			
11-	Location of teaching the course:	Faculty of Pharmacy-Sana'a University			



III. Course description:

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2. Discuss the factors affecting gastrointestinal absorption of drugs.
3. Identify the role of dosage form on drug bioavailability.
4. Identify the factors affecting drug absorption, distribution and elimination.
5. Identify bioavailability and bioequivalence.
6. Utilization the effect of absorption, distribution, metabolism, and excretion (ADME) of drugs in the body for dosage optimization and evaluating drug dosage regimen.
7. Demonstrate the biopharmaceutical considerations in drug product design.
8. Recognize the relationship between product design and the drug absorption, distribution and elimination.
9. Predict the effect of excipients and food on drug absorption, distribution and elimination.
10. Analyze the results of the in-vitro and in-vivo studies.
11. Assess physicochemical characteristics of drug substances as a factor affecting drug absorption.
12. Analyze bioavailability and bioequivalence studies.
13. Examine the biopharmaceutical consideration in dosage form design.
14. Communicate the dosage adjustment with physicians, suggesting therapeutic monitoring plans for physicians and use different information sources to solve medication problems.
15. Retrieve information from a variety of sources, including libraries, databases and internet.



16. Work effectively in a team and demonstrate time management skills.

V. Course Content:

1 – Course Topics/Items:

a – Theoretical Aspect

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2	Drug Absorption, Mechanisms of Drug Absorption	a1,a2, b1,b2,b3, b4,d1,d2,d3	Definition, Mechanisms of drug absorption process, factors affecting absorption	1	2
3	Physiologic Factors Related to Drug Absorption	a3,a4, b2,b3,b4, d1,d2,d3	Types of factors pH, gastric and GIT factors	1	2
4	Physiochemical Factors Related to Drug Absorption	a4, b2,b3,b4, d1,d2,d3	Nature of drug, drug solubility, dissolution and drug stability	1	2
5	Biopharmaceutical Aspects of The Active Pharmaceutical	a4, b2, d1,d2,d3	Formulation factors, method	1	2



	Ingredient And Pharmaceutical Equivalence		of manufacture, excipients, drug dosage and dosage regimen		
6	Drug Distribution Physiologic Drug Distribution and Protein Binding	a4, b1,b2,b3,b4, d1,d2,d3	Definition, parameters, volume of distribution, Mechanisms , factors and Clinical Application	1	2
7	Mid-term Exam	a1-4, b1-4		1	2
8	Drug Metabolism	a3,a4,a5, b1,b2,b3,b4 d1,d2,d3	Definition and parameters,	1	2
9	Pharmacogenetics and Drug Metabolism	a5, b3,b4, d1,d2,d3	Mechanisms, classification and factors	1	2
10	Drug Excretion	a5, b1,b2,b3,b4, d1,d2,d3	Definition and parameters,	1	2
11	Drug Elimination, Clearance, and Renal Clearance	a4, b3,b4, d1,d2,d3	Mechanisms, classification and factors	1	2
12	Drug Elimination and Hepatic Clearance	a4, b3,b4, d1,d2,d3	Mechanisms, types and factors	1	2
13	Bioavailability	a2,a3,,a5, b1,b2,b3, b4,d1,d2,d3	Definition, classification, Relative bioavailability, Absolute bioavailability parameters and evaluations	1	2
14	Bioavailability and Bioequivalence	a2,a3, b1,b2,b3,b4, d1,d2,d3	Model parameters , drug absorption and bioavailability of dosage forms.	1	2



15	Biopharmaceutic Considerations in Drug Product Design and in Vitro Drug Product Performance	a3, b1,b2,b3, d1,d2,d3	Pharmaceutical alternative, Pharmaceutical equivalent	1	2
2.	final-term Exam	a1-5, b1-4		1	2
Number of Weeks /and Units Per Semester				16	32

b- Practical Aspect:				
Order	Practical Tasks	CILOs (symbols)	Number of weeks	Contact hours
1	Biopharmaceutic considerations in drug product design	c1, d1,d2,d3	1	2
2	Practice how stomach emptying, GI residence time, and gastric window affect drug absorption	c1,c2,c3,c4, d1,d2,d3	1	2
3	Determine the drugs for which gastric pH can affect bioavailability	c1,c2,c3, d1,d2,d3	1	2
4	Determine the particle size, crystal form, solubility, dissolution, and ionization affect in vivo dissolution and absorption.	c1,c2,c3,c4, d1,d2,d3	1	2
5	Dissolution test methods and relation to in vivo performance.	c1,c2,c3,c4, d1,d2,d3	1	2
6	Determine the simulating drug distribution in the body	c1,c2,c3,c4, d1,d2,d3	1	2
7	Mid-term exam	c1-4	1	2
8	Determine the formulation factors and manufacturing method affecting PE and TE.	c2,c3,c4, d1,d2,d3	1	2
9	Practice use plasma or urine data to calculate fraction of drug excreted and metabolized.	c2,c3,c4, d1,d2,d3	1	2
10	Practice use plasma or urine data to calculate fraction of drug excreted and metabolized.	c2,c3,c4, d1,d2,d3	1	2



11	Practice application of the physiologically factors include understanding the effect of renal impairment	c1,c2,c3,c4, d1,d2,d3	1	2
12	Practice drug elimination and hepatic clearance Application of the physiologically factors include understanding the effect of hepatic clearance	c4, d2 d1,d2,d3	1	2
13	Determine the methods of drug excretion from the body	c4, d1,d2,d3	1	2
14	Determine the select API from multiple sources while meeting PE (pharmaceutical equivalence) and TE (therapeutic equivalence) requirement as defined in CFR. How pharmaceutical equivalence affects therapeutic equivalence and Pharmaceutical alternatives.	c1-4, d1,d2,d3	1	2
15	Bioavailability and bioequivalence test methods, and analysis.	c2-4, d1,d2,d3	1	2
2.	Final-term exam	c1-4	1	2
Number of Weeks /and Units Per Semester			16	32

VI- a-Teaching strategies of the course:

Lecture method, Group Discussion, Problem solving sessions, tutorials, brainstorming and Practical sessions.

b- Assessment Methods:

Oral Exam, Quizzes, Attendance, Participation, Short answers, reports, homework, Written exam, Practical works, practical exam and practical reports.

VII. Assignments:

No.	Assignments	Aligned CILOs (symbols)	Week Due	Mark
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1	Homework Assignments	a1-5, b1-4, d1-3	Sporadic through the semester	10
2	Reports	c1-4, d1-3		

VIII- Schedule of Assessment Tasks for Students During the Semester:

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes (CILOs symbols)
8.	Attendance, Participation and quizzes	All Weeks	10	7%	a1-5,b1-4, d1-3
9.	Oral Tests and Homework-assignments	Sporadic through the semester	10	7%	a1-5, b1-4, d1-3
10	Attendance, Practical Reports	All Weeks	15	10%	c1-4
11	Practical mid-semester exam	7 th	15	10%	c1-4
12	Theoretical mid-semester exam	7 th	30	20%	a1-4, b1-4
13	Final Exam (theoretical)	16 th	50	33%	a1-5, b1-4
14	Final Exam (practical)	16 th	20	13%	c1-4
Total			150	100%	

IX. Students' Support:

Office Hours/week	Other Procedures (if any)
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2 hours per week

X. Learning Resource (MLA style or APA style)S:

5- Required Textbook(s) (maximum two)

- 1- Notes on biopharmaceutics prepared by the department staff.
- 2-Shargel, L and Yu, ABC., 2016, *Applied Biopharmaceutics & pharmacokinetics*, 7th edition, McGraw-Hill Education, New York.
- 3-Bauer, LA, 2008, *Applied clinical pharmacokinetics*, 2nd edition, McGraw-Hill Companies, Inc, New York.

6- Recommended Readings and Reference Materials

- 1-Rowland M, Tozer T, 1995, *Clinical Pharmacokinetics—Concepts and Applications*, 3rd ed, Lea & Febiger, Philadelphia.
- 2-Levine RR, 1990, *Drug Actions and Reactions*, 4th ed., Little, Brown, Boston.
- 3- Gibaldi, M. (1991) *Biopharmaceutics and Clinical Pharmacokinetics*, 4th edn. Lea & Febiger, Philadelphia.

7- Electronic Materials and Web Sites etc.

www.pubmed.com
<http://www.sciencedirect.com/>

8- Other Learning Material:

J Pharmacokinet Biopharm
J Pharm Sci
Published articles related to the discussed topics
United States Pharmacopeia and National Formulary (latest edition) United States Pharmacopeial Convention Inc., Rockville, MD.
British Pharmacopoeia (latest edition), HMSO. London.
Martindale, W. (latest edition) *The Extra Pharmacopoeia.*, Royal Pharmaceutical Society Great Britain, London.

XI. Facilities Required:



1 - Accommodation:	- Well-equipped lecture halls with data show facilities, whiteboards, etc. - Well-equipped laboratories with all required equipment and slide.
2 - Computing resources:	- Computer laboratory with internet facilities.

XII. Course Improvement Processes:

7- Strategies for Obtaining Student Feedback on Effectiveness of Teaching

- Student-based assessment of the effectiveness of teaching using a questionnaire designed by the Quality Assurance Unit at the end of the semester.
- Meeting with students and faculty (once per semester).

8- Other Strategies for Evaluation of Teaching by the Instructor or by the Department

- Assessment of the course syllabus and contents by the teachers using a questionnaire designed by the Quality Assurance Unit of the university at the end of the semester.
- Regular meeting and discussion of the course content between the Head of Department and the teaching staff of the course (for theory and practice).

9- Processes for Improvement of Teaching.

- Revision of the course specification and its teaching strategies every three academic years after consideration of all issues raised by the teachers and/or students during regular meetings and discussions.
- Exploring any possible defects in the course that might be encountered by the teaching staff and their mitigation in subsequent improved versions of course specification.

10- Processes for Verifying Standards of Students' Achievement

- Checking of a sample of students' work by an independent faculty member.
- Periodic exchange and check marking of a sample of students' assignments with a faculty member from another institution.
- Adoption of scoring rubrics to assess the students' achievement (both for ongoing or summative assessments).
- Regular follow-up of laboratory logbooks to assess the practical achievement of students.

11- Procedures for Periodically Reviewing of Course Effectiveness and Planning for Improvement

- Student rating and feedback
- Peer rating and feedback
- Regular meeting of the Curriculum Committee of the faculty.

6- Course Development Plans

- Conducting regular workshops for the staff for improving their course specification skills.



	<ul style="list-style-type: none">▪ Regular revision of course specification and syllabus items.
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XIII. Course Policies:	
1	Class Attendance: <ul style="list-style-type: none">▪ Attendance of all lectures and practical sessions is required. Unexcused absence exceeding 25% of the lectures or practical sessions will disqualify the student from entering the final exam.
2	Tardiness: <ul style="list-style-type: none">▪ Non-reasonable frequent tardiness will be allowed and is considered as absence from the lectures/
3	Exam Attendance/Punctuality: <ul style="list-style-type: none">▪ Exam attendance is obligatory unless being excused by the department and faculty.▪ Absence from assignments or exams will be dealt with according to the general policy of the university.
4	Assignments & Projects: <ul style="list-style-type: none">▪ Assignments: Written and oral; Laboratory logbook signed by the responsible demonstrator.▪ Projects: Not applicable.
5	Cheating: <ul style="list-style-type: none">▪ Punishment of cheating will be according to the general policy of the university in this respect.
6	Plagiarism: <ul style="list-style-type: none">▪ Plagiarism in written essays, reports, etc. is not accepted, and students who plagiarize the works of others will be punished according to the general policy of the university.
7	Other policies: <ul style="list-style-type: none">▪ General policies of the Students' Affairs of the University and the Quality Assurance Unit.